REMARKS/ARGUMENTS

Reconsideration of this Application and entry of this Amendment after Final are respectfully requested. The proposed amendment places the claims in better form for appeal. Additionally, this amendment addresses items brought up by the examiner in the final office action. In view of the amendments and following remarks, favorable consideration and allowance of the application is respectfully requested.

Claims 1-3, 6-10, 12-16 and 18-25 are pending. Claims 1 and 12 have been amended. Claim 11 has been canceled. Support for the amendments may be found in the specification at least at paragraph [0012]. No new matter has been introduced by virtue of the amendments. The amendments are made solely to advance prosecution of this application and should not be construed as concurrence or agreement with the claim rejections under reply.

35 U.S.C. §102 Rejection

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the . . . claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Thus, to warrant the §102(b) rejection, the references cited by the Examiner must show each and every limitation of the claims in complete detail. The Applicant respectfully asserts that the cited reference fails to do so.

Claims 1-3, 7-13, 15, 16 and 19-25 have been rejected under 35 U.S.C. 102(b) as being anticipated by Schwarz et al., U.S. Patent 6,368,658 (Schwarz). Applicant respectfully traverses. Applicant submits that Schwarz does not teach or disclose:

A medical implant for the controllable delivery of at least one pharmaceutical compound to a localized area within a patient, said implant comprising:

an implantable medical device having a surface and a coating formed on at least a portion of said surface, said coating having at least two polymer layers, two of said at least two polymer layers incorporating at least one releasable pharmaceutical compound, each of said two polymer layers incorporating at least one releasable pharmaceutical compound having at least one physical property affecting the releasability of said releasable pharmaceutical compound that differs

from said other layer, wherein said at least one physical property affecting the releasability of said at least one pharmaceutical compound is molecular weight, as required by currently amended claim 1, or

A method for making a controllable drug releasing gradient coating for the surface of a medical device, said method comprising the steps of:

forming a first polymer layer on said surface of said medical device, said first polymer layer containing at least one releasably bound pharmaceutical compound and having at least one physical property affecting the releasability of said at least one pharmaceutical compound; and

forming at least one additional polymer layer on said first polymer layer, said at least one additional layer containing at least one releasably bound pharmaceutical compound, said additional polymer layer differing in said at least one physical property affecting the releasability of said at least one pharmaceutical compound from said first polymer layer, wherein said at least one physical property affecting the releasability of said at least one pharmaceutical compound is molecular weight, as required by currently amended claim 12.

Schwarz teaches that a pharmaceutical compound may be included in a polymer layer used to coat a medical device and that a barrier layer of polymer (without pharmaceutical agent) may be used to control release of the pharmaceutical agent from the underlying layer. Schwarz also teaches that the release profile of the drug may be "altered by concurrently applying several layers of gradient concentrations to yield a multi-phasic release profile." (See Example 4). Schwarz does not teach that there should be at least two polymer layers of differing molecular weight, each containing drug, and that the drug release is affected by the differing molecular weights of the polymers. Accordingly, Applicant submits that Schwarz does not anticipate independent claims 1 and 12. Claims 2, 3, 7-10, 15, 16 and 19-25 depend from independent claims 1 or 12 and add further limitations thereto and are patentable for at least the reasons presented above with respect to the independent claims. The Examiner is respectfully requested to withdraw the Section 102 rejection over Schwarz.

35 U.S.C. §103 Rejections

To maintain a proper rejection under 35 USC § 103, the Examiner must meet four conditions to establish a prima facie case of obviousness. First, the Examiner must show that the prior art

suggested to those of ordinary skill in the art that they should make the claimed composition or device or carry out the claimed process. Second, the Examiner must show that the prior art would have provided one of ordinary skill in the art with a reasonable expectation of success. Both the suggestion and the reasonable expectation of success must be adequately founded in the prior art and not in an applicant's disclosure. Third, the prior art must teach or suggest all the claim limitations. *In re Vaeck*, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991). Fourth, if an obviousness rejection is based on some combination of prior art references, the Examiner must show a suggestion, teaching, or motivation to combine the prior art references ("the TSM test"). In re Dembiczak, 50 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 1999). Following *KSR Int'l Co. v. Teleflex, Inc.*, this fourth prong of the *prima facie* obviousness analysis must not be applied in a rigid or formulaic way such that it becomes inconsistent with the more flexible approach of *Graham v. John Deere*, 383 U.S. 1, 17-18 (1966); 127 S. Ct. 1727 (2007). It must still be applied, however, as the TSM test captures the important insight that "a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *Id.* at 1741 (citing *United States v. Adams*, 383 U.S. 39, 50-52 (1966)).

The cited references, even when combined do not teach or suggest all of the limitations of the pending claims as currently amended.

Claims 6 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwarz. Applicant respectfully traverses. As discussed above with regard to the Section 102 rejection, Schwarz does not disclose all of the features of independent claims 1 and 12, as currently amended. Claims 6 and 18 depend from claims 1 and 12, respectively. Accordingly, regardless of whether it would be obvious to employ polymers having the molecular weights specified in claims 6 and 18, this rejection must fail because the basic underlying features of the claimed invention are not taught or suggested by Schwarz. The Examiner is respectfully requested to withdraw the Section 103 rejection over Schwarz.

Claim 14 stands rejected under 35 U.S.C. Section 103(a) as being unpatentable over Schwarz in view of Sirhan et al., U.S. Patent 6,858,221 (Sirhan). Applicant respectfully traverses. As discussed above with regard to the Section 102 rejection, Schwarz does not disclose all of the features of independent claim 12, as currently amended. Sirhan does not cure this. Claim 14 depends

from claim 12. Accordingly, regardless of whether Sirhan teaches a self-expanding stent used to deliver a pharmaceutical compound, this rejection must fail because the basic underlying features of the claimed invention are not taught or suggested by Schwarz or Sirhan, or both references taken together. The Examiner is respectfully requested to withdraw the Section 103 rejection over Schwarz in view of Sirhan..

Conclusion

For the foregoing reasons, Applicant believes all the pending claims are in condition for allowance and should be passed to issue. The Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. 1.17, or credit any overpayment, to Deposit Account No. 01-2525. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at telephone (707) 543-5021

Respectfully submitted,

/Alan M. Krubiner, Reg. No. 26,289/
Alan M. Krubiner
Registration No. 26,289
Attorney for Applicant

Medtronic Vascular, Inc.
3576 Unocal Place
Santa Rosa, CA 95403
Facsimile No.: (707) 543-5420